## REMARKS

Applicants have now had an opportunity to carefully consider the Examiner's comments set forth in the Final Office Action of July 20, 2009.

Reconsideration of the Application is requested.

Claims 1-10 are pending in the application.

Claims 1 and 4 have been amended.

New claim 10 is added.

## The Office Action

Claims 1-7 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,952,010 to Constantz.

Claims 8 and 9 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,952,010 to Constantz, in view of Hall, Bone: Fracture Repair and Regeneration, *CRC Press, Inc.*, Vol. 5, pp. 161-162 (1991).

For the reasons outlined below, it is submitted that the claims are in condition for allowance.

**Claim 1** recites a method of producing a bone substitute material in the form of a block predominantly composed of carbonate apatite for medical use, which comprises the step of forming carbonate apatite by contacting a block of calcium compound with a phosphate-containing solution, wherein said calcium compound block contains substantially no powders such that powders with a diameter of 20 micrometers or smaller are less than 1.0% by weight. At least one of said calcium compound block and said phosphate solution contains a carbonate group, and wherein the method does not include any sintering step.

Support for the amendments to claim 1 are to be found in the specification at page 7, lines 9-10 and 16-18.

Constantz discloses paste compositions capable of setting into carbonated apatite (title). The compositions can be prepared such that they are flowable, moldable, and capable of hardening in situ (summary). There is no suggestion that the dry

components of Constantz form a block.

The Examiner asserts that the uniform dispersion produced has substantially no powder. There is no suggestion that in the paste or clay-like mixture of Constantz be formed such that powders with a diameter of 20 micrometers or smaller are less than 0.8% by weight, as now claimed.

The Examiner refers to col. 5, lines 3-5 of Constantz, which discloses a monophasic product with a single crystal structure. There is no suggestion of contacting this hardened product with a phosphate-containing solution. Further, even if it were, there is no suggestion that powders with a diameter of 20 micrometers or smaller are less than 1.0% by weight.

Further, the dry ingredients of Constantz are mixed with a liquid to form a paste. There is no suggestion as to how a paste, which passes through a needle in the range of about 10-18 gauge, preferably about 14-16 gauge (see, Constantz, col. 6, lines 30-35), could be formed unless the dry ingredients were in the form of a fine powder which could be expected to include particles with a diameter of 20 micrometers or smaller.

Accordingly, it is submitted that claim 1, and claims 2, 3, 7, 8, and 10 dependent therefrom, distinguish over Constantz.

Dependent **Claim 8** recites that the block is porous and has an average pore diameter in a range of 50-1000μm.

Constantz makes no suggestion of a porous block with an average pore diameter in a range of 50-1000μm. Rather Constantz uses a finely comminuted starting material generated by ball milling, rolling, or the like. The Examiner cites Hall (Brian Hall, "Experimental Investigation on Pore Size and Pore Distribution," in Bone Fracture Repair and Regeneration, Vol. 5, pp. 161-162 (1991)), accessed through Google Books. The brief extract from Hall refers to chrome-cobalt alloy implants and cites to prior references as suggesting an appropriate pore size of 50-400μm or a minimum of 100 or 150μm.

The Examiner argues that it would have been obvious to modify the "device" of Constantz with a pore diameter in the range of 50-1000μm in view of Hall to mimic bone tissue and allow for osteon formation. The Examiner fails to explain how the paste or milled dry materials of Constantz could be made with any particular pore size, and in

particular, the pore size of Hall's metal alloy. In particular, since the Constantz paste is delivered to the implant site through a fine needle, pores in the paste cannot be controlled. Further, control of the pores in the paste, even if it were possible, would have little or no bearing on the size of the pores in the hardened body formed after implanting the paste. In contrast, in Hall, it is presumed that a pre-shaped body is implanted. Further, Hall provides no indication of there being any relationship between pore size in the alloy implant prior to and after its solidification.

Accordingly, it is submitted that claim 8 distinguishes patentably and unobviously over Constantz in view of Hall.

**Claim 4** recites a bone substitute material which is produced by method which includes forming carbonate apatite by contacting a block of calcium compound with a phosphate-containing solution, wherein said calcium compound block contains substantially no powders such that powders with a diameter of 20 micrometers or smaller are less than 1.0% by weight, wherein at least one of said calcium compound block and said phosphate solution contains a carbonate group, and wherein the method does not include any sintering step, and wherein the bone substitute material is predominantly composed of carbonate apatite with carbonate group content of 0.5% or more by weight.

Constantz discloses is a paste which may be hardened. There is no suggestion that powders with a diameter of 20 micrometers or smaller are less than 1.0% by weight of the Constantz paste or clay. The resulting material of Constantz is thus expected to differ substantially from the presently claimed material.

**Claim 9** recites a method of producing a bone substitute material predominantly composed of carbonate apatite. The method includes providing a porous body formed of a calcium compound, the body containing substantially no powders and having an average pore diameter in a range of 50-1000μm. The porous body is contacted with a phosphate-containing solution. At least one of the porous body and phosphate solution contains a carbonate group, whereby the porous body is predominantly composed of carbonate apatite.

Constantz makes no suggestion of forming a bone substitute material from a body having an average pore diameter in a range of 50-1000μm, which after contacting with a phosphate solution, is predominantly composed of carbonate apatite.

The Examiner argues that it would have been obvious to modify the "device" of Constantz with a pore diameter in the range of 50-1000μm in view of Hall to mimic bone tissue and allow for osteon formation. The Examiner fails to explain how the paste or milled dry materials of Constantz could be made with any particular pore size, and in particular, the pore size of Hall's metal alloy. In particular, since the Constantz paste is delivered to the implant site through a fine needle, pores in the paste cannot be controlled. Further, control of the pores in the paste, even if it were possible, would have little or no bearing on the size of the pores in the hardened body formed after implanting the paste. In contrast, in Hall, it is presumed that a pre-shaped body is implanted. Further, Hall provides no indication of there being any relationship between pore size in the alloy implant prior to and after its solidification. Thus, one of ordinary skill in the art could not reasonably envisage any method for incorporating the pore size of Hall into the very-differently produced product of Constantz.

Accordingly, it is submitted that claim 9 distinguishes over the references of record.

## CONCLUSION

For the reasons detailed above, it is respectfully submitted all claims remaining in the application (Claims 1-10) are now in condition for allowance.

☒ Remaining Claims, as delineated below:

| (1) FOR | (2) CLAIMS REMAINING AFTER AMENDMENT LESS HIGHEST NUMBER PREVIOUSLY PAID FOR | | (3) NUMBER EXTRA |
|---|---|---|---|
| TOTAL CLAIMS | 10 | - 20 = | 0 |
| INDEPENDENT CLAIMS | 3 | - 3 = | 0 |

Respectfully submitted,

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